EMBRACING TECHNOLOGY: FDA RELEASES DRAFT GUIDANCE ON DECENTRALIZED CLINICAL TRIALS

On May 2, 2023, in a move intended to accelerate the adoption of digital health technologies, the U.S. Food and Drug Administration ("FDA") released draft guidance regarding the conduct of decentralized clinical trials ("DCTs") for drugs, biological products and devices. This draft guidance expands on previous FDA recommendations released in the midst of the COVID-19 pandemic.

BACKGROUND

A DCT is a clinical trial in which some or all trial-related activities occur at locations other than traditional trial sites. DCTs may be implemented as fully decentralized, in which all clinical activities are remote, or as a hybrid model, in which only some of the clinical activities are remote. Non-traditional sites may include locations such as participants' homes or local health care facilities.

FDA supports the implementation of DCTs, with FDA Commissioner Robert Califf stating that DCTs have the potential to "enhance convenience for trial participants, reduce the burden on caregivers, expand access to more diverse populations, improve trial efficiencies, and facilitate research on rare diseases and diseases affecting populations with limited mobility."

GUIDANCE

The regulatory requirements for DCTs and traditional site-based clinical trials are the same. The guidance outlines recommendations for implementing DCTs but does not impact the regulatory standards.

However, DCTs can introduce some additional issues. The guidance describes DCT-specific considerations that may not be present in site-based clinical trials, and how sponsors can approach such issues. The guidance assists sponsors in evaluating their clinical trial procedures through the lens of decentralized activities. DCTs often present novel problems that sponsors conducting site-based clinical trials have not previously encountered.

The guidance is intended to assist sponsors in evaluating: (i) DCT design; (ii) remote visits and related activities; (iii) digital health technologies; (iv) roles and responsibilities; (v) informed consent and IRB oversight; (vi) investigational products; (vii) packaging and shipping considerations; (viii) safety monitoring plan; and (ix) software use.

PRACTICAL TAKEAWAYS

1. Sponsors should evaluate how to ensure DCT participants have access to any necessary digital health technology. Participants may have varying levels of access to smartphones, reliable internet connectivity, etc. Sponsors may also need to provide instructions or educational materials for participants less familiar with certain technologies. For health care institutions conducting DCTs, considerations include compliance with fraud and abuse and beneficiary inducement requirements.
2. Sponsors may need to implement additional data security procedures to handle and store the large amounts of data likely to be generated by a DCT. Research institutions may need to consider how sponsor security requirements will integrate with the health care entity's security standards.
3. Investigational products must be administered under the supervision of the investigator or a subinvestigator per 21 C.F.R. § 312.61. Sponsors should consider whether administration of the investigational product outside of a clinical trial site is appropriate, or whether remote oversight of administration of the investigational product is appropriate.
4. Whether a DCT can be conducted entirely with remote activity will depend on the type of assessments and procedures needed to collect endpoints and monitor safety.
5. Sponsor responsibilities are the same for DCTs and site-based clinical trials.

If you have any questions or would like help organizing a decentralized clinical trial, please contact:

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